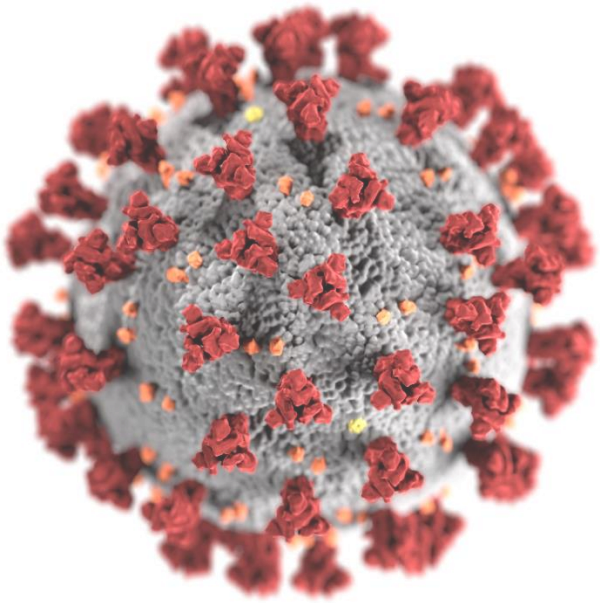
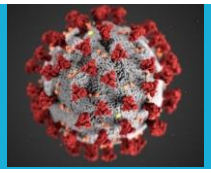


COVID-19 Vaccination Playbook

DELAWARE

DELAWARE COVID-19 Vaccination Planning Team
16 OCTOBER 2020

DELAWARE COVID-19 VACCINATION PLAYBOOK



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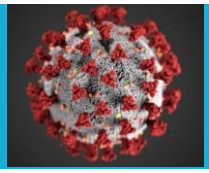
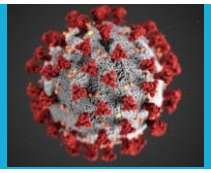


Record of Changes

Date of original version:

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
09/18/20	N/A	09/22/20	Assignment of Sections	DPH
09/24/20	N/A	09/30/20	Draft of Sections	DPH
10/01/20	1	10/07/20	Initial Review of Playbook	DPH
10/07/20	2	10/09/20	CDC Review for Preliminary Feedback	CDC
10/12/20	3	10/14/20	Review with CDC Feedback	DPH
10/14/20	4	10/16/20	Review prior to CDC Submission	DPH
10/16/20	5	10/16/20	Final Review prior to CDC Submission	DPH
10/17/20	N/A	10/26/20	DE COVID-19 Vaccination Task Force	DPH
10/17/20	6	10/26/20	CDC Technical Review	CDC
10/26/20	7		Review with CDC Feedback	DPH



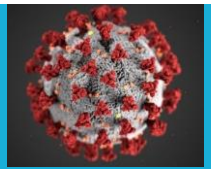
Introduction

Delaware, located on the eastern Atlantic coast of the United States, occupies part of the Delmarva Peninsula between Delaware Bay and Chesapeake Bay, and was one of the thirteen original states. Delaware is divided into three counties: New Castle, Kent, and Sussex. Historically, industrialized New Castle County has contrasted with the other two counties, which have been predominantly agricultural areas. Today approximately 60% of the population lives in New Castle County, the northernmost county. Wilmington, the state's largest city, with more than 70,000 people, is in New Castle County. Dover, located in Kent County in the center of the state, is the capital of Delaware.

According to the 2019 Delaware Population Consortium, the population of Delaware is 972,332. This represented an increase of 8.3% percent over the 2010 census figure of 897,934. Delaware's beaches and boardwalks make the state a popular tourist destination during the summer months. The southern portion of the state, particularly the coastline in Sussex County, sees an increase in its summer population. In addition to the tourists that visit the coastline, Delaware is host to thousands of foreign students employed by local businesses to assist with the economic boost associated with the tourism influx. These students staff restaurants, retail stores, and other associated businesses in and around the most heavily affected tourist destinations.

During this current COVID-19 pandemic effective allocation and administration of a future vaccine will play a vital role in reducing COVID-19 effects on Delaware's health, society, and economy. Although the overarching aim of the Delaware Division of Public Heath's vaccination program is to vaccinate all persons in Delaware who choose to be vaccinated, the initial vaccine supply will be insufficient to meet this goal.

The Delaware Department of Health and Social Services (DHSS), Division of Public Health (DPH), is a unique organization in terms of the responsibility, size, and scope of operations. While most states have municipal or county health departments in addition to a state health department, DPH serves as the public health entity for both state and local activities.



Section 1: COVID-9 Vaccination Preparedness Planning

Instructions:

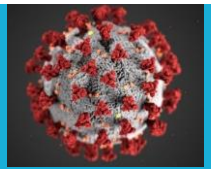
A. *Describe your early COVID-19 vaccination program planning activities, including lessons learned and improvements made from the 2009 H1N1 vaccination campaign, seasonal influenza campaigns, and other responses to identify gaps in preparedness.*

Since the COVID-19 outbreak, the Immunization Program has been working internally to improve its processes if the vaccines were to be facilitated through the program. During normal operations, each position in the program had a singular purpose, but with an advancing vaccine response forthcoming, the Immunization Program needed to make some changes. One such change was the personnel structure. With the increased need of dose level accountability, several personnel have been cross trained to assist with vaccine inventory, ordering and storage and handling of the vaccine. Our two CDC Public Health Advisors and the two health program Representatives will be educated on the intricacies of maintaining dose level accountability into the Immunization Information System, which is referred to as DelVAX. During our last CDC site visit in 2019, additional staff were recommended by the CDC and were budgeted in the 2020 Cooperative to assist with vaccine management and to increase our storage and handling presence in the community.

With the messaging from the CDC remaining consistent about how the vaccine was going to be handled, it gave the Immunization Program time to work on a process that has been slow to achieve, which is to decrease the time it takes to report immunization data to the IIS from a community clinic or Point of Dispensing (POD) exercise. The program has worked with the CDC and the IIS vendor, Envision Technologies, to create a system to where administered immunization data can be reported directly from a clinic site. This process was not part of the COVID-19 response, but it aligned with current response activities. This new process will allow real time submission into the IIS if a Wi-Fi connection is available. If not, the administered data can be uploaded to the IIS at the end of the clinic day

DPH has held weekly internal meetings since the release of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – one for the DPH COVID-19 Vaccination Advisory Committee which is comprised of many members from the Influenza Advisory Committee and one for DPH leadership. DPH has also met with certain stakeholders such as Delaware Public Health and Medical Ethics Advisory Group, Delaware Healthcare Association, Healthcare Associated Infection Advisory Committee, Post-Acute Care Task Force, Healthcare Preparedness Committee, to provide a preliminary approach to COVID-19 vaccine distribution while awaiting further guidance from the federal level given their anticipated involvement during the initial delivery of vaccine.

B. *Include the number/dates of and qualitative information on planned workshops or tabletop, functional, or full-scale exercises that will be held prior to COVID-19 vaccine availability. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program.*



Dose level accountability was an issue of concern during the H1N1 campaign, where many doses went to sites that were not enrolled as vaccinating providers, and these doses could not be tracked by the Immunization Program. With the increased attention to dose level accountability, through the creation of a new CDC Vaccine Tracking System (VTrckS), a dose of vaccine can be traced from the time it leaves the CDC Vaccine Depot, arrives at a provider site, and then is reported to the IIS as a dose that was administered. Delaware's Immunization Information System (IIS), known as DelVAX has the ability to accept either the Unit of Use, or Unit of Sale information submissions, using Health Level 7 (HL7) protocol messages to allow for flexibility in dose level accountability.

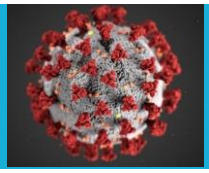
Reporting of immunizations has been a manual process of reporting by paper to the Immunization Program for several years. With the CMS Meaningful Use initiative, it gave providers an opportunity to connect their Electronic Medical Record to the IIS. While this has been a successful project, it has not been a quick one, with an average time of 34 days required to onboard providers using HL7 messaging. Even with this short amount of time, Delaware still has several providers reporting manually. The Immunization Program continues to reach out to onboard providers, with an estimated completion date of December 31, 2020.

Increased participation will involve the COVID-19 vaccine enrollment process, outreach to providers, and development of an online training program, and these initiatives are currently in place to support the transition process, which is anticipated to be ongoing as we evolve to complete electronic reporting after COVID-19. The program also has worked with the CDC and the IIS vendor, Envision Technologies, to create a system to where administered immunization data can be reported directly from a clinic site. State Service Centers that house the DPH public health clinics wanted to get the responses from the questions prior to vaccination, and this new enhancement will allow us to do that.

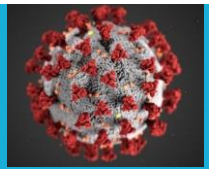
DPH plans to develop the Delaware COVID-19 Vaccination Task Force to engage additional internal and external partnerships in the operational and logistical processes specific for vaccine distribution, with its first meeting on October 23, 2020. Additional subcommittees and groups would be developed as the need arises, including the insertion of vaccine distribution discussions in established COVID-19 working groups involving health systems, long-term care, corrections, mental health, community groups, faith-based organizations, commercial pharmacies, other governmental agencies, schools and institutes of higher education, professional organizations, and businesses. Many of these groups already have COVID-19 vaccination as a standing agenda item, so these discussions will continue to evolve as more information is available for planning.

A tabletop exercise for DPH is planned for Oct. 29, 2020, to focus on internal processes. Another exercise for the Delaware COVID-19 Vaccination Task Force will be scheduled after its introductory meeting on Oct. 23, 2020, and will be focused more on vaccine operations involving these stakeholders such as professional medical organizations, health systems, Federally Qualified Health Centers (FQHCs), third-party payers, health care associations, community groups, and other governmental agencies.

C. *Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program*



The Delaware COVID-19 Vaccination Program Committee is a diverse and well-rounded group, with every organization committed to providing vaccine for immunization in the most efficient manner. The key objective for this initiative is that processes in the COVID-19 vaccination program be fluid and adaptable to be able to fit every situation as changes occur. While a tabletop exercise is scheduled for Oct. 29, 2020, to review and walk through some of the objectives, specifically when it comes to critical populations and vaccine allocation additional exercises will be planned as frequently as needed in order to achieve the best outcome. Many different scenarios, including those involving operational, logistical, political, and technological/informatic challenges, must be tested and approved to develop processes before implementation in order to achieve desired goals. Once implementation begins, each process should be screened for validity and be modified as situations warrant. Continuously retesting processes during implementation will allow for the phasing out of issues as they arise, ensuring that processes meet the objective. Process will be reviewed and discussed during the weekly vaccine planning committee meetings to ensure that every step that needs to be corrected is identified and presented to the committee for resolution.



Section 2: COVID-19 Organizational Structure and Partner Involvement

A. *Describe your organizational structure.*

Using the Division of Public Health's (DPH) current organizational chart (Appendix C), the Office of the Medical Director (OMD) is taking lead, with the Immunizations Program and Emergency Medical Services and Preparedness Section (EMSPS) supporting the required processes and reporting up to OMD through the structure. The State's State Health Operations Center (SHOC) also has the organization structure (Appendix D) to show the responsible agencies responsible for different areas when activated for the vaccine response.

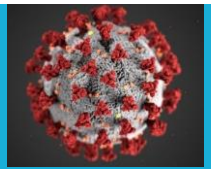
B. *Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.*

DPH has held weekly internal meetings since the release of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – one for the DPH COVID-19 Vaccination Task Force which comprises of many members from the Influenza Advisory Committee and one for DPH leadership, within which many members are part of the COVID-19 Vaccination Task Force to ensure coordination between the two main groups. DPH has also met with certain stakeholders such as the Delaware Public Health and Medical Ethics Advisory Group, Delaware Healthcare Association, Healthcare Associated Infection Advisory Committee, Post-Acute Care Task Force, Healthcare Preparedness Committee, to provide a preliminary approach to COVID-19 vaccine distribution while waiting for further guidance from the federal level given their anticipated involvement during the initial delivery of vaccine. .

The current team for influenza vaccine planning encompasses expertise in mass vaccination and pandemic planning/response (OMD, Immunizations, EMSPS, Community Health, etc.) so that this team is the appropriate conduit to expand into COVID-19 vaccination. Also, key members of the Pandemic Task Force and H1N1 response will be involved, which include:

- DPH Office of Communications
- Office of the Medical Director
  - Immunization Program
  - Office of Infectious Disease Epidemiology (OIDE)
  - Office of the State Epidemiologist
- Emergency Medical Services and Preparedness Section
- Delaware Attorney General's Office
- Office of the Governor Constituent Affairs

As mentioned above, an internal public health leadership call has been occurring weekly and as of October 23rd, additional external partners will be added.



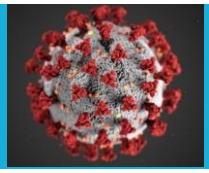
C. *Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.*

Partnerships created during the COVID-19 response specifically for testing – testing collaboratives, Pandemic Resurgence Advisory Committee, etc. – will also be engaged in vaccination initiatives as the objectives are similar, especially regarding access by vulnerable populations. Partnership include Division of Public Health, Delaware Emergency Management Agency, other state agencies, health care systems, FQHCs, governmental representatives, academic universities, professional organizations, community organizations, etc. Also, existing partnerships related to immunizations and influenza, such as the Healthcare Associated Infection Advisory Committee and the Immunization Coalition of Delaware, provide subject matter expertise in clinical and operational aspects of vaccination distribution. The Delaware Public Health and Medical Ethics Advisory Group was involved in the review of the priority groups for H1N1 vaccination and will be included for COVID-19 to allow for transparency and standardization of prioritization, with its first meeting regarding COVID-19 vaccination scheduled on November 2, in anticipation of finalized guidance from federal partners on approach to allocation.

DPH plans to develop the Delaware COVID-19 Vaccination Task Force to engage additional internal and external partnerships in the operational and logistical processes specific for vaccine distribution, with its first meeting on Oct. 23, 2020. Additional subcommittees and groups would be developed as the need arises, including the insertion of vaccine distribution discussions in established COVID-19 working groups involving health systems, long-term care, corrections, mental health, community groups, faith-based organizations, commercial pharmacies, other governmental agencies, schools and institutes of higher education, professional organizations, and businesses.

D. *Identify and list members and relevant expertise of the internal team and the internal/external committee.*

Experts will include, but are not limited to, those from health systems, medical community, community-based organizations, correctional facilities, homeless shelters, faith-based leaders, FQHC's, Governor's Office, legislators, academic institutions, health care associations, professional organizations, commercial pharmacies, etc., for which many are currently involved in COVID-19 testing strategies, with goals to include others as appropriate. Many of these stakeholders have been invited to participate in the COVID-19 Vaccination Task Force given experience with the current COVID-19 pandemic, the previous novel H1N1 influenza pandemic, public health, mass vaccination, crisis standard of care, community health and vulnerable population needs, delivery of health care, and communications, with others already participating in other groups involved in COVID-19 planning and response that can become



subcommittees to support the overall COVID-19 Vaccination Program. The introductory meeting for the COVID-19 Vaccination Task Force is scheduled on Oct. 23, 2020.

E. *Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.*

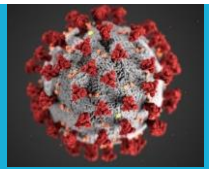
Collaboration has been on-going between state and federal authorities through the HHS Region III (State Health Officers), specifically the Region III Vaccine Task Force, and various weekly to monthly calls with partners such as CDC, HHS, ASTHO, etc. The State Medical Director has been assigned as the designated state lead for vaccine distribution planning, with scheduled calls with federal and national partners (CDC, HHS, ASTHO, etc.) on a weekly to monthly basis based on the call. Since DPH is the only designated health department in Delaware, it is responsible for local public health activities as well and will continue to work in that same capacity with local partners. One advantage to this structure is that DPH does not need to coordinate with a local public health entity to reach the community level, and DPH has been successful in maintaining those relationships and communication channels with individual communities.

F. *Describe how your jurisdiction will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban Indian organizations.*

The Immunization Program Manager has reached out to both tribal communities, hoping to discuss current COVID activity, and the need to immunize their population. These tribes are small and are integrated into the communities, whereas in other states tribes may live on reservations or have access to the Indian Health Services. Representation from both the Lenape Indian Tribe of Delaware and Nanticoke Indian Tribe has been included in the DPH COVID-19 Vaccination Task Force, and further outreach to these communities will continue to enhance engagement.

G. *List key partners for critical populations that you plan to engage and briefly describe how you plan to engage them, including but not limited to:*

- Pharmacies – Walgreens, CVS, Rite Aid
- Correctional facilities/vendors – Delaware Department of Corrections
- Homeless shelters – DHSS Division of State Service Centers (Hotels) and Housing Alliance are communicated with at least monthly via meetings and phone conversations
- Community-based organizations – National Coalition of 100 Black Women
- Faith-based leaders – similar organizations for testing opportunities
- FQHCs – Westside Family Health, LA Red Health Center, Henrietta Johnson Medical Center
- Health systems – Delaware Healthcare Preparedness Coalition members and their internal SME's for vaccination efforts



- EMS/Police/Fire – Engaging with county paramedic agencies to become Closed PODs for first responder agencies.
- Delaware Public Health and Medical Ethics Advisory Group – prioritization groups for vaccine

DPH has a list of contacts for these partners and will either invite them to our discussions or offer to participate in their meetings to share information and expertise.

Section 3: Phased Approach to COVID-19 Vaccination

Instructions:

A. *Describe how your jurisdiction will structure the COVID-19 Vaccination Program around the three phases of vaccine administration:*

Phase 1: Potentially Limited Doses Available

Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand

Phase 3: Likely Sufficient Supply, Slowing Demand

The State Health Operations Center (SHOC) understands there may be significant challenges with vaccine distribution especially in phase 1 in which there may be a limited number of doses available. The state will follow the CDC recommended priority groups listing for distribution. In preparation the state has been in discussion with strategic partners (especially hospitals, first responders etc.) regarding the need to prioritize those individuals that need and want to be vaccinated.

The state will follow the Vaccine Allocation Annex to determine the specific amount of vaccine that will be allocated to each priority grouping. This process is listed below and is part of the state's Crisis Standards of Care Concept of Operations.

Section 3.1: Vaccine Allocation Annex to the Delaware Division of Public Health Crisis Standards of Care Concept of Operations

1.0 Purpose

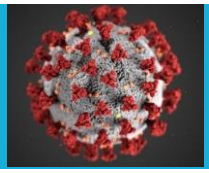
1.1. The purpose of this annex to the *Delaware Crisis Standards of Care Concept of Operations* (*Crisis Standards of Care CONOPS*) is to guide the ethical allocation of vaccine(s) and medications during a pandemic when supplies of vaccine(s) and/or medications are not adequate to treat the entire population of Delaware.

1.2. The *Vaccine Allocation Annex* should be utilized for vaccine allocation guidance when the *Crisis Standards of Care CONOPS* has been implemented to assist with ethical triage and decision-making during a pandemic event.

1.3. The *Vaccine Allocation Annex* should be utilized during the activation of the *Delaware Pandemic Influenza Plan* and other related plans in support of the Public Health Capability domain of Medical Countermeasure Dispensing and Administration.

1.4. This Annex is designed to provide guidance while working in coordination with other plans processes and procedures. This Annex does not supersede other existing Delaware Division of Public Health (DPH) plans or procedures.

2.0 Vaccine/Medication Priority Populations



2.1. DPH, with recommendations from the Delaware Public Health and Medical Ethics Advisory Group (Ethics Group) will review the CDC list of prioritized population groups and determine allocation and distribution of vaccine(s).

2.2. Priority workforce groups will include, but are not limited to the following:

2.2.1. Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.

2.2.2. Healthcare workers

2.2.3. Public Safety/Emergency Services including, but not limited to the following:

A. Law Enforcement (LE)
B. Emergency Medical Services (EMS)
C. Fire/Rescue Departments (FD)
D. Corrections
E. National Guard (NG)
F. Other

2.2.4. Public Health and Community Health support workers

2.2.5. Critical Infrastructure workers including, but not limited to:

A. Manufacturing operations deemed essential
B. Supply chain (warehousing and shipping)
C. Food supply chain
D. Utilities and other services

2.2.6. Essential workers (as defined by Delaware State of Emergency declarations, Public Health Emergency declarations, etc.)

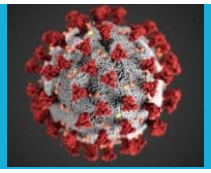
A. Manufacturing
B. Public facing employees such as grocery stores, banks, etc.
C. Food Service
D. Retail
E. Others

2.3. Priority population groups will include, but are not limited to the following:

2.3.1. Population(s) most at risk for the following:

A. Susceptibility
B. Spreading
C. Hospitalization
D. Mortality

2.3.2. Congregate facilities



A. Long-Term Care/Rehabilitation
B. Prisons
C. Schools, including colleges and universities
D. Other facilities

2.3.3. Populations most at risk for severe illness of death

A. Age groups (over age 65)

B. Health disparities

1. Densely populated areas
2. Multi-generation households
3. Healthcare access limited
4. Co-morbidities

a. Medical
b. Mental Health
c. Substance Use disorders

5. Lack of insurance
6. Language and cultural barriers
7. Fixed income
8. Homeless population

2.3.4. Tourist/high travel geographic areas at risk for spreading disease outside of the local area

2.3.5. Other

3.0 Allocation Decision-making

3.1. Each pandemic has specific levels of risk based on transmissibility, clinical severity, co-morbid and socioeconomic factors. The Ethics Group will evaluate each pandemic event individually to determine the appropriate guidance.

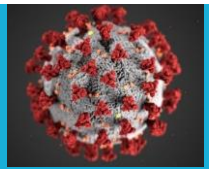
3.2. The Ethics Group will provide guidance for vaccine(s)/medication allocation based on the following framework:

3.2.1. Transmissibility[1]

A. Direct

1. Direct Contact
2. Droplet Spread

[1] Lesson 1: Introduction to Epidemiology. Section 10: Chain of Infection. Retrieved from https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section10.html. June 4, 2020.



B. Indirect

1. Airborne
2. Vehicle-borne
3. Vector-borne (mechanical or biological)

3.2.2. Clinical Severity[2]

A. Fatality rate (% of deaths per capita)
B. Hospitalization rates (% of hospitalizations per capita)
C. Hospitalization to Fatality ratio (number of deaths per hospitalization state-wide)

3.2.3. Prioritized population groups (refer to Tab A) by Tiers[3]. Transmissibility and Severity considerations play a critical role in determining priority groups.

A. During times of limited availability, Tiers may be prioritized into Sub-Tiers to determine ethical allocation.

1. Tier 1- Highest priority for prophylaxis or treatment to save lives and protect public health and safety. This Tier may include, but is not limited to:

a. Individuals most at risk for death or severe illness
b. Healthcare providers
c. Public health workers and their families
d. Emergency services workers and their families
e. Individuals most at risk for contracting and spreading the illness

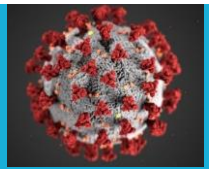
2. Tier 2- Priority group for prophylaxis or treatment of those individuals who most at risk for hospitalization or who provide support for critical infrastructure activities. This Tier may include, but is not limited to:

a. Individuals most at risk for hospitalization due to the illness
b. Critical infrastructure support and manufacturing
c. Food chain workers

3. Tier 3- Priority group for prophylaxis and/or treatment for reduction in illness severity to reduce hospitalization time. This Tier may include, but is not limited to:

a. Hospitalized individuals with minimal exacerbation risk

[2] Novel Framework for Assessing Epidemiological Effects of Influenza Epidemics and Pandemics. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3557974/. June 4, 2020.
[3] Allocating & Targeting Pandemic Influenza Vaccine. Guidance Development and Revision. Retrieved from https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/guidance.html. June 5, 2020.



b. Essential workers such as:

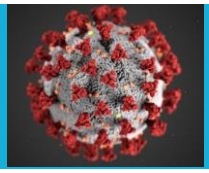
- Groceries
- Pharmacies
- Food service
- Auto and home maintenance
- Supply chain
- Other

c. Community support (local, county and state)

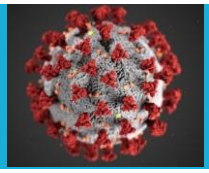
4. Tier 4- Priority group for prophylaxis and/or treatment primarily to prevent reoccurrence of the epidemic/pandemic. This Tier should include all those individuals who are appropriate to receive prophylaxis and/or treatment but were not included in the other Tiers.

3.2.4 The Ethics Group will develop recommendations for vaccine(s)/medication allocation based the above framework, to include priority and sub-priority groups as needed. The recommendations will be provided through the State Health Operations Center (SHOC) or appropriate DPH chain of authority.

3.2.5 SHOC and/or DPH will develop an allocation and distribution plan in coordination with the *Delaware Pandemic Influenza Plan,* the *Delaware Division of Public Health Mass Distribution of Medications/Vaccines Standard Operating Guideline,* and other applicable plans, procedures and guidelines.



Phase One	Tier 1	1a	Closed POD agreements	• Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home. (Examples include -Direct care hospital staff, First responders, LTC providers, etc)
		1b	Closed POD agreements PH vaccination clinics	• Other essential workers critical to maintain the healthcare system who cannot work from home (examples include – other hospital staff, dispatchers, vaccinators, emergency management staff etc) • Persons over age 65 who are at risk for severe disease (examples include – those living in congregate settings, having co-morbidity illness, working outside of the home etc) • Persons with underlying medical conditions that are risk factors for severe COVID-19 illness
		1c	Closed POD agreements PH vaccination clinics	• Public health and community health support workers • Critical infrastructure workers • Congregate care (Examples include- prison workers and inmates, group homes etc)
		1d	Closed POD agreements PH vaccination clinics	• Other critical infrastructure as listed in Emergency Declarations (example – poultry plants) • Other high-risk populations such as racial and ethnic minority groups
Phase Two	Tier 2	2a	PH vaccination clinics Provider Networks	• Remainder of Phase 1 populations • Persons with limited access to routine vaccination services
		2b		• Persons with limited access to routine vaccination services • Persons who work within critical services (listed above) who can work from home
Phase Three	Tier 3		Providers	• Essential workers such as: (groceries, pharmacies, food service, auto and home maintenance, Supply chain, other) • Community support (local, county and state)
Phase Three	Tier 4		Providers	• General population not addressed above



Section 4: Critical Populations

Instructions:

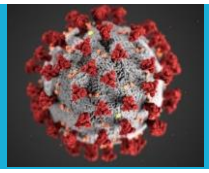
A. *Describe how your jurisdiction plans to: 1) identify, 2) estimate numbers of, and 3) locate (e.g., via mapping) critical populations. Critical population groups may include:*

- *Healthcare personnel*
- *Other essential workers*
- *Long-term care facility residents (e.g., nursing home and assisted living facility residents)*
- *People with underlying medical conditions that are risk factors for severe COVID-19 illness*
- *People 65 years of age and older*
- *People from racial and ethnic minority groups*
- *People from tribal communities*
- *People who are incarcerated/detained in correctional facilities*
- *People experiencing homelessness/living in shelters*
- *People attending colleges/universities*
- *People living and working in other congregate settings*
- *People living in rural communities*
- *People with disabilities*
- *People who are under- or uninsured*

Several divisions, sections, and programs across the state, and specifically within the Delaware Department of Health and Social Services (DHSS), will be able to assist the state in identifying, estimating numbers of, and locating critical populations. The DHSS Division of Healthcare Quality and Control oversees long-term care & assisted living facilities. The Delaware DPH Community Health Services section will use trusted members in vulnerable communities to connect with this group. The Medical Director with the Department of Corrections can provide information on correctional facilities. The DHSS Division of Developmental Disabilities Services and Division of Services for Aging and Adults with Physical Disabilities maintain information on this population. The DHSS Division of Medicaid & Medical Assistance, as well as several programs within the Division of Public Health, provides assistance to those who are under- or uninsured. The state will connect with programs and sections that serve specific populations, such as those mentioned above, to better understand these populations.

The internal workgroup is connecting with statewide divisions, sections, and programs to identify, estimate numbers of, and locate critical populations. The DPH Community Health Services section has existing partnerships with several of the populations described above, such as people from racial and ethnic minority groups, and can assist in identification, estimating numbers of, and locating critical populations.

Identifying, estimating numbers of, and locating critical populations are critical to determining the resources needed during the early phases of vaccination, including the number of vaccine



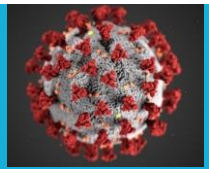
doses, and the approach to vaccine administration. The resources and approach to administration will evolve as the vaccine supply expands.

Broadly speaking, epidemiologists with the state currently leverage various data sources, such as the My Healthy Community data portal, to identify, estimate numbers of, and locate critical populations and subpopulations impacted by COVID-19. Epidemiological data sources provide demographic information such as age, sex, race and ethnicity, which will allow for identification of critical populations. Epidemiologists have been collecting surveillance data and conducting case investigations since March 2020; this data provides a wealth of information about the demographics of COVID-19 cases in the state and may provide insights into critical populations that can be served by the COVID-19 vaccine.

Since July 2020, Delaware has onboarded 16 new epidemiologists, data analysts, and public health professionals to assist with conducting the state's COVID response. The current COVID Epidemiology team includes a Data Team comprised of 3 epidemiologists and 2 data analysts and is overseen by the State's Deputy Epidemiologist. The Data Team meets twice weekly to review data-related activities, such as analyzing testing event data. Additionally, the Data Team disseminates daily outbreak detection reports which drill down into specific locations and populations that may be at risk for COVID-19. The State Deputy Epidemiologist provides a daily update to state public health leadership on the number of new cases overall and by demographic group and geographic region. Thus, the results produced by the Data Team help create a better understanding of the state's critical populations and will be used to inform vaccine allocation/distribution efforts in the coming months.

B. *Describe how your jurisdiction will define and estimate numbers of persons in the critical infrastructure workforce, which will vary by jurisdiction.*

The State will utilize connections with health systems, Emergency Medical Service agencies, and employers of other essential personnel to estimate the number of persons in the critical infrastructure workforce, including identifying subgroups of individuals at greater risk for COVID-19. The State will solicit input from employers to determine who is included in the critical infrastructure workforce. Throughout the remainder of the calendar year and into 2021, as the vaccine becomes available for distribution to certain populations, the State will engage in the aforementioned activities to estimate the number of persons in the critical infrastructure workforce and incorporate this group with critical populations into the prioritization process. The State has already sent out an online survey through the Medical Society of Delaware (see Section 5 below for greater detail) to assist with provider recruitment and enrollment. Information gathered in the survey includes the number of staff at numerous health care organizations and practices across the state, therefore providing insight on the number of people in the critical infrastructure workforce as it relates to health care. The state is in a unique position as it has a centralized health department (i.e., one department for the whole state as opposed to county or local health departments), and therefore has more streamlined channels



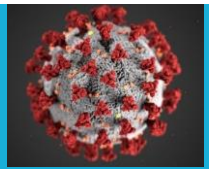
of communication to partners across the state. Decisions about dissemination of information and coordination of immunization-related activities occur at the state level, which allows for a more timely and coordinated response as there are fewer avenues of communication to maintain.

Delaware hospitals are in the process of determining estimates for prioritizing groups by a) number of direct patient care, b) support for direct patient care, C) essential employees that cannot work from home and may come in contact with COVID patients, and d) others. Estimates for first responders (EMS/Fire/Police/Dispatch) have been completed. DPH is currently in the process of contracting with a vendor to assist with estimating vulnerable population numbers, with the expectation to have these data available prior to vaccine availability anticipated, as of the initial creation of this document, to be in November.

C. *Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.*

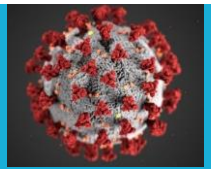
The Delaware DPH Emergency Medical Services and Preparedness Section will provide recommendations for vaccine allocation in subset groups of critical populations if there is insufficient vaccine supply. Given that there is likely to be substantial overlap between subgroups critical populations identified above, targeted efforts may focus on specific populations most at-risk. The state will also communicate with community leaders across the state to identify subset groups of critical populations based on COVID-19 prevalence and the status of the virus among these groups. The DHSS and DPH staff, including leadership and epidemiologists, will maintain communication with employers of members of prioritization groups in Phase 1A and 1B, such as health care systems, schools, and food packaging and distribution plants. Over the next several weeks, the state will work with employers to estimate the number and composition of subset groups of critical populations based on vaccine availability. The state has already collected some of this information with the survey mentioned above and described in greater detail below (Section 5). Key metrics of COVID-19 in the state at the time that the vaccine becomes available, such as prevalence, positivity rate, and demographics of those infected, will also help identify additional subset groups of critical populations.

The DPH Ethics Advisory Group will be activated to provide recommendations to the DPH Director when vaccine is in insufficient supply to administer to all members within the identified critical populations. The DPH Ethics Advisory Group will also take into consideration the current ACIP workgroup recommendations, in order to make decisions about additional subset groups of critical populations. The state will solicit input from employers of critical populations (such as health care workers) about specific subgroups that are most at risk for COVID-19 within the overall critical population.



D. *Describe how your jurisdiction will establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the critical population groups.*

Community Health Services and the EMSPS Vulnerable Populations Coordinator within DPH will leverage existing relationships with community leaders who advocate for their communities, which may include individuals at increased risk for COVID-19. The State has created many partnerships with community members and leaders prior to and during COVID-19 and will use these partnerships to identify points of contact (whether the current ones or new ones based on needs and expertise) within the critical population groups. Leadership and staff within Community Health Services can use their connections with community members to establish communication methods within critical population groups as appropriate.



Section 5: COVID-19 Provider Recruitment and Enrollment

Instructions:

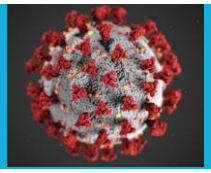
A. *Describe how your jurisdiction is currently recruiting or will recruit and enroll COVID-19 vaccination providers and the types of settings to be utilized in the COVID-19 Vaccination Program for each of the previously described phases of vaccine availability, including the process to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

To recruit interested providers, an online survey link was sent through the Medical Society of Delaware newsletter, Delaware Health Alert Network (DHAN), the email addresses of long-term care (LTC) contacts, and kidney/dialysis centers in Delaware. The survey responses are used to determine interest and capacity to administer COVID-19 vaccine to patients and staff. Once the provider has received and agreed to completing the COVID-19 vaccinator checklist, they will be eligible for enrollment. The survey was released on September 1, 2020 without a deadline. The program will continue to monitor responses and enroll potential providers on a rolling basis. As of October 13, 2020, 190 responses were collected with 130 respondents expressing interest in administering COVID-19 to either patients, staff or both.

Once the vaccination provider has been identified through the recruitment process, Phase 1 providers will be sent the enrollment form to be filled out and returned and loaded into VTrckS before November 1, 2020. Phase 2 and Phase 3 providers will receive an email containing a link to COVID-19 enrollment documents within the State IIS (DelVAX), which is still under construction by the DelVAX vendor, Envision Technologies. Both the Provider Agreement and Provider Profile information are in DelVAX as a PDF and can be downloaded for signature of the Chief Medical Officer (CMO) and Chief Executive Officer (CEO). The enrollment template in DelVAX is built to require an Immunization Program User (user from the program approving the enrollment) to confirm the medical license. The medical license will be verified by the program user utilizing the Delaware Division of Regulation License Look-Up webpage https://delpros.delaware.gov/oh_verifylicense. The information on this website will verify that the license is valid and supplies the issue and expiration date.

Utilizing the online survey, interested providers will be screened to verify their specialty (i.e. Geriatric, Family medicine, LTC, etc.), approved vaccine storage units and staffing capacity to ensure proper vaccination of patients. Additionally, the provider will be screened to ensure their patient demographics meet one of the three criteria: People at increased risk for severe COVID-19 illness; People at increased risk of acquiring or transmitting COVID; or People with limited access to routine vaccination services.

B. *Describe how your jurisdiction will determine the provider types and settings that will administer the first available COVID-19 vaccine doses to thitical population groups listed in Section 4.*



DPH is currently collaborating with EMS agencies in the three counties on initiatives to administer vaccine in closed POD-type settings for established critical populations. The state EMS agency is making preparations to have adequate infrastructure and supplies to simultaneously hold three PODs at once. See Section 4C. DPH has established Closed POD agreements with hospitals, health care systems and 1st responder agencies to positively affect the administration of vaccine to critical work force populations. Hospitals have demonstrated with 2019 flu vaccine efforts that they can vaccinate approximately 75% of their workforce within three (3) days.

C. *Describe how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) or JavaScript (JSON) template via a SAMS-authenticated mechanism.*

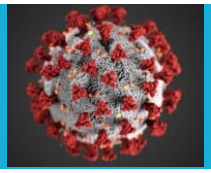
The vaccinating providers will enter their enrollment data and upload this information directly into DelVAX. Once this information is reviewed and approved, it will be downloaded directly to CDC using IIS. The DelVAX Vendor, Envision Technologies, is currently working to finalize the enrollment template. Once finalized, Envision Technologies will develop a data extraction tool that will submit data directly to CVRS. A reporting template from CDC has been provided to Envision Technologies in order to create this functionality within DelVAX, with an expectation of this functionality being added to DelVAX by November 7, 2020.

D. *Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

The State Immunization program will use the information reported on the CDC COVID-19 Vaccination Program Provider Profile Information Form to verify that the medical license number(s) are active and valid to both possess and administer vaccines by checking this information with the Delaware Division of Regulation License Look-Up webpage https://delpros.delaware.gov/oh_verifylicense. A printable version of the verification is available and can be saved with the provider enrollment information. If any of these provider's licenses are found to be invalid or if the provider is unable to possess or administer vaccines the CMO and/or the CEO will be notified that the identified provider will not be able to administer and/or receive vaccine until the license information can be updated or resolved. Pharmacist licenses on enrollment forms will be verified through information provided by the Bureau of Regulation.

E. *Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.*

Providers will be notified of all required trainings through correspondence with the primary vaccine coordinators identified at every enrolled CDC COVID-19 vaccine provider site. Prior to the enrollment process, providers that do not report administered doses electronically via HL7 or flat file will have to complete training for direct data entry into DelVAX. There is currently a Training Material module built into DelVAX which contains training guidance (Quick Reference Guides) for vaccine ordering and inventory management, CDC's You Call the Shots, and a



Reports Training section that contains training information on using the Reminder/Recall functions within DelVAX. Training documents for the provider enrollment process are currently being developed. The You Call the Shots training materials will be updated to address specific COVID-19 vaccination once CDC makes this information available. The Immunization program will require the providers to submit their training certificates from CDC "You Call the Shots" training to the program office. Completion of all other required provider trainings will be self-reported from the vaccinating providers by utilizing and submitting a completed Provider Training form to the program. This data will be entered into an Access or EXCEL data-base so it can be monitored.

F. *Describe how your jurisdiction will approve planned redistribution of COVID-19 vaccine (e.g., health systems or commercial partners with depots, smaller vaccination providers needing less than the minimum order requirement).*

All COVID- 19 vaccine transfers will be coordinated through the Immunization Program utilizing a process similar to what is outlined in the transfer of publicly funded vaccines guidance and will be provided to all vaccinating provider sites regarding the procedures and requirements for redistribution of COVID-19 vaccines. This guidance will adhere to the Vaccine Transport section of the CDC Vaccine Storage and Handling Toolkit (see Appendix A). Once the Provider contacts the Immunization program via email or phone requesting to redistribute vaccine, the provider will be emailed a Vaccine Transfer Form (See Appendix B) to complete and return it to the Immunization program.

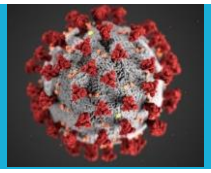
G. *Describe how your jurisdiction will ensure there is equitable access to COVID-19 vaccination services throughout all areas within your jurisdiction.*

The DPH Ethics Group will be consulted, along with the DPH Health Equity Bureau to assess availability of vaccine to provide for equitable access. The final prioritization algorithm will be shared with stakeholders and published in a future version of the vaccination plan.

H. *Describe how your jurisdiction plans to recruit and enroll pharmacies not served directly by CDC and their role in your COVID-19 Vaccination Program plans.*

Pharmacies are consistently enrolled in DelVAX. Designated staff identify smaller pharmacies and train those sites for enrollment in DelVAX. The Delaware Board of Pharmacy is a partner the program will use to ensure all pharmacies have had an opportunity to enroll in DelVAX. Presently, there are less than five small pharmacies that are not enrolled in DelVAX. The State does not anticipate using these pharmacies during phase 1.

Additionally, Delaware pharmacies are actively contacting the Immunization Program to express interest in becoming a COVID-19 vaccination partner. Pharmacy contact information is being collected and will be used once more COVID-19 vaccine information becomes available. An on-boarding process will be established, which will include license verification through the Bureau of Regulation.



Section 6: COVID-19 Vaccine Administration Capacity

Instructions:

A. *Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.*
B. *Describe how your jurisdiction will use this information to inform provider recruitment plans.*

The Delaware Division of Public Health (DPH) will utilize the Pandemic Vaccination Campaign Planning Tool to help determine the vaccination capacity for the COVID-19 vaccine response for the State of Delaware. The results of the tool should help to target where the vaccine can be most effectively used. The results from this tool will be used for a discussion in the COVID vaccination planning group to determine the best course in providing COVID-19 vaccinations in every phase of the response. If effective, the State of Delaware should be able to ascertain the time it will take to vaccinate the adult population in the State of Delaware.

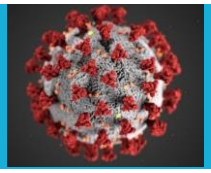
The DPH Office of Preparedness will reach out to the health systems during the week of October 12, 2020, to discuss vaccine planning and allocation. Further outreach to other agencies will be accomplished as progress is reported to the Vaccine Planning Committee.

The Immunization Program will enter the information into the planning tool once a consensus is reached on the following areas:

1. Population to be vaccinated
2. Provider vaccination groups
3. Provider group vaccination scenarios
4. Vaccine availability
5. Vaccine allocation
6. Monthly vaccine availability

Once the data is entered and agreed upon, the vaccination planning group can use the information to determine the strengths and shortfalls in providers groups starting in Phase 1 of the response. Knowing the capacity of the provider groups is key, especially in determining to what extent that other provider groups (Example: Pharmacies supporting community clinics) can supplement to fill in the gaps to optimize vaccine availability and allocation. This is especially important in Phase 1 of the response, as the goal is to vaccinate this population as quickly as possible using the vaccine that is available.

Once the state enters Phases 2 & 3, and vaccine becomes more readily available, the vaccination planning group can use the data from the planning tool, data from the CDC program Tiberius, and data from the Data Lake to forecast coverage rates, completion dates for differing age groups and have the ability to target areas of need.



Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

Instructions:

A. *Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.*

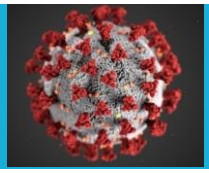
Once guidance regarding the Delaware Ethics Groups recommendations concerning vaccine allocation has been reached, the Vaccine Planning Committee will meet to discuss the decisions of the committee, and how much vaccine will be distributed to the applicable populations. With the meeting of the Advisory Committee on Immunization Practices (ACIP) on October 28, 2020, the Delaware Public Health and Medical Ethics Advisory Group will be meeting on November 2, 2020, to review any guidance or statements regarding prioritization groups and vaccine allocation from the ACIP meeting.

B. *Describe your jurisdiction's plan for assessing the cold chain capability of individual providers and how you will incorporate the results of these assessments into your plans for allocating/assigning allotments of COVID-19 vaccine and approving orders.*

- As part of the enrollment process, specific information regarding vaccine storage capabilities and equipment will be collected.
- The Immunization Information System (IIS), known as DelVAX has an Asset Management functionality that will be utilized for those providers capable of uploading temperature monitoring data via a .csv file. The goal is to maintain similar procedures that already exist and are familiar to providers (e.g., protocols from the Vaccine for Children (VFC) Program).
- Information collected during enrollment will include type of storage unit (pharmacy grade, household, commercial, etc.); temperature capabilities of the storage units; temperature monitoring equipment (hospital based system, continuous temperature monitoring, etc.); capacity; and appropriate equipment and training to transfer vaccine if necessary.

C. *Describe your jurisdiction's procedures for ordering COVID-19 vaccine, including entering/updating provider information in VTrckS and any other jurisdictional systems (e.g., IIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.*

Entering/ Updating Provider Information in VTrckS and DelVAX:



- Providers will be created in VTrckS and DelVAX (IIS) utilizing information obtained from the COVID-19 Vaccine Provider Enrollment Initiation form.
- Once providers are established in VTrckS, provider information will be updated by ExIS file upload from the DelVAX Master Date File (twice daily).

Allocations:

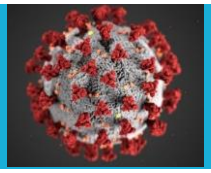
- Allocations will be managed in a process similar to the influenza vaccine allocations. Provider orders are submitted and entered onto an order template (excel spreadsheet).
- Doses requested or allocated are totaled. If all doses can be ordered, all orders are processed utilizing the template via VTrckS order upload.
- If only a percentage can be processed due to limited allocation, that percentage is established for the doses needed, keeping in mind the minimum dose requirement.
- Balances are determined and the spreadsheet is maintained as a master file in order to send balances once the allocation is updated.

D. *Describe how your jurisdiction will coordinate any unplanned repositioning (i.e., transfer) of vaccine.*

- The Immunization Program staff trained and experienced in vaccine transfers will utilize an approved process for transferring vaccine. Immunization Program staff responsible for transferring vaccine will be trained on storage and handling of ultra-cold COVID vaccine utilizing revised guidance from CDC.
- Specific providers may be authorized by the Immunization Program to transfer vaccine from one location to another within their organization.
- All transfers are coordinated and approved by the Immunization Program staff.
- Vaccine transfers are entered in DelVAX under the Inventory Management module.
- Vaccine Transfer reports may be accessed using DelVAX' s Inventory Transfer Inquiry.
- Entities must sign and agree to conditions in the *CDC COVID-19 Vaccine Redistribution Agreement* for the sending facility/organization and have a fully completed and signed *CDC COVID-19 Vaccination Provider Profile* for each receiving location.

E. *Describe jurisdictional plans for monitoring COVID-19 vaccine wastage and inventory levels.*

- COVID-19 vaccine waste and inventory levels will be monitored utilizing VTrckS allocation reports daily and requiring vaccine wastage reporting via DelVAX.
- DelVAX COVID-19 vaccine inventory reconciliation will be required weekly
- DelVAX Inventory Management reports will be utilized by Immunization Program staff to monitor inventory levels.

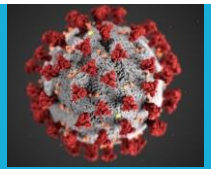


Section 8: COVID-19 Vaccine Storage and Handling

Instructions:

A. *Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels:*

- *Individual provider locations*
  i. As part of the enrollment process, specific information regarding vaccine storage capabilities and equipment will be collected.
  ii. Information collected during enrollment will include type of storage unit (pharmacy grade, household, commercial, etc.); temperature capabilities of the storage units; temperature monitoring equipment (hospital based system, continuous temperature monitoring, etc.); capacity; and appropriate equipment and training to transfer vaccine if necessary. Hospital Systems will be contacted about Ultra Low Cold Temperature capacity.
- *Satellite, temporary, or off-site settings*
  i. Any satellite or temporary site location will have the appropriate vaccine storage unit for the type of vaccine that is being administered. Digital data logging equipment will be with the storage unit to track the temperature of the vaccine at these locations.
  ii. The Immunization staff will provider trainings on vaccine storage and handling and for all personnel responsible for the management of the vaccine before these temporary vaccination sites are conducted. A manual with the CDC Storage and Handling Toolkit information and temperature excursion information will be provided to the team leads of these clinics.
- *Planned redistribution from depots to individual locations and from larger to smaller locations*
  i. The Preparedness Warehouse Depot will have the appropriate vaccine storage unit for the type of vaccine that is being stored and administered. Digital data logging equipment will be with the storage unit to track the temperature of the vaccine at these locations.
  ii. All personnel responsible for the management of the vaccine will have the appropriate training on vaccine storage and handling from program and CDC resources.
  iii. Local transport of vaccine from one location to another within the jurisdiction may be necessary but should only occur only on a limited basis. Only enrolled providers with an approved Redistribution Agreement will be permitted to redistribute COVID-19 vaccine. An approved Redistribution Agreement must include Standard Operating Procedures describing the process for validating cold-chain procedures in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling.
- *Unplanned repositioning among provider locations*

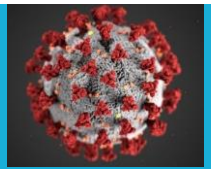


i. Any surplus vaccine among provider locations, except for approved redistribution providers, will be transported back to the Preparedness Warehouse Depot in the appropriate transport equipment by Immunization Program Personnel.

B. *Describe how your jurisdiction will assess provider/redistribution depot COVID-19 vaccine storage and temperature monitoring capabilities.*

Primarily, the redistribution will be managed and conducted by the Immunization Program staff who are trained and experienced in vaccine transfers. The staff will utilize the current State-approved process for transferring vaccine. In some case, specific providers may be authorized by the Immunization Program to transfer vaccines from one location to another within their organization. These provider transfers must be approved and coordinated by the Immunization program staff prior to transporting any vaccine. Those providers that are approved to transport vaccines, have demonstrated to the program that they have the proper vaccine transport unit and temperature monitoring devices to redistribute the vaccines and the knowledge of packing out the vaccines as described in the CDC Vaccine Management Toolkit.

The Emergency Preparedness Team is surveying large hospital groups to determine if they can store the vaccines at the ultra-cold temperatures. If so, the plan would be to direct ship to these sites to avoid the need to redistribute. It is not recommended to transport vaccines that need ultra-cold chain temperatures to maintain viability; however, vaccine can be kept for five days (120 hours) between 2°C and 8°C to allow for off-site vaccine administration. If the shipping container is used for vaccine storage, the manufacturer recommends only opening the shipping container twice a day. Vaccine stored in a refrigerator should be used first before additional vials are removed from frozen storage as vaccine cannot be refrozen once thawed. Vaccine should also be shielded from light. Vaccines vials should have beyond-use dates (BUDs) documented prior to transport of vaccine.



Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Instructions:

A. *Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.*

Delaware will be utilizing its Immunization Information System, DelVAX.

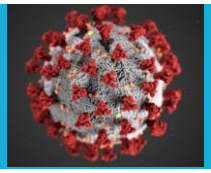
B. *Describe how your jurisdiction will submit COVID-19 vaccine administration data via the Immunization (IZ) Gateway.*

Delaware has approved and submitted the CONNECT DUA. Delaware has received a confirmation email that the onboarding for the IZGateway Connect is complete for Delaware. In a recent conference call with Delaware's IIS vendor, Envision Technology Partners, Delaware was informed that vaccine administration data would no longer be reported via Connect to CDC but via a flat file (CVRS Covid-19 Vaccine Reporting Specifications) to the CDC Data Clearinghouse. This is according to information the IIS vendors have received from CDC. Delaware's IIS vendor is committed to providing this extract flat file for Delaware. Having just received the layout and required data elements, Delaware's IIS vendor is currently working to create a process that will collect all the required data elements, create an exportable file that can be loaded into CDC's Data Clearinghouse. Delaware expects to be able to load a test file to the CDC by November 16, 2020, and a production file by November 25, 2020. CDC has offered technical support as needed.

C. *Describe how your jurisdiction will ensure each COVID-19 vaccination provider is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.*

Providers who are currently onboarded with DelVAX to submit vaccine administration data via their EMR/EHR system will continue to report in this manner. Those providers who have not onboarded with DelVAX will be required to perform direct data entry of doses administered. Training for provider staff will be provided.

D. *Describe the steps your jurisdiction will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.*



Delaware has purchased and is implementing a mobile application that is ready for implementation. This will allow patient registration, vaccination reporting and inventory management that can be used at satellite, temporary, or off-site clinic settings.

E. *Describe how your jurisdiction will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours as well as steps to be taken when providers do not comply with documentation and reporting requirements.*

Where possible, providers will be set up as Type III full inventory providers where doses will be decremented from inventory, dose by dose, as the administration is being recorded. Those sites not set up as full inventory (i.e. Vaccine for Children Program providers are aggregate reported currently and will need to remain aggregate even if receiving COVID-19 vaccine), the Immunization Program will be utilizing DelVAX reports (i.e., doses administered, Patients Detail with Services, inventory reconciliation, etc.) to monitor vaccine inventory and reporting.

F. *Describe how your jurisdiction will generate and use COVID-19 vaccination coverage reports.*

DelVAX contains many "canned" reports that can be utilized by Delaware to monitor and evaluate COVID-19 vaccination distribution, storage/handling, administration and reporting. Some example reports available are:

Reminder/Recall

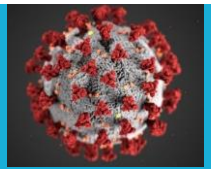
Patients with Vaccine Refusals

Doses Administered

Immunization Rates

Vaccine Shipments/order status/returns inquiry/return status.

Delaware also has the availability to create ad-hoc reports as needed by Delaware's IIS vendor through the vendor contract



Section 10: COVID-19 Vaccination Second-Dose Reminders

Instructions:

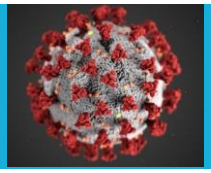
A. *Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.*

There will be three methods of second-dose reminders for COVID-19 vaccine recipients. First, providers will receive instruction/training regarding the importance of documenting accurate information on vaccine record cards provided to patients receiving the COVID-19 vaccine.

Second, the state IIS registry, DelVAX, has reminder/recall functionality, which providers may use to send reminder letters to their patients with valid addresses in DelVAX.

Finally, the program plans to contract second-dose reminders with a vendor that can automate reminders via phone call or SMS from patient contact information collected from DelVAX. At this time, immunization program staff are entering into a contract with OneCallNow for implementation of patient second-dose reminders.

Training will be provided to vaccinators to ensure they are entering complete address information and accurate phone numbers into patient demographic sections of their Electronic Medical Records and/or DelVAX. The Immunization program will encourage pharmacies and provider offices that have their own reminder re-call systems to utilize this functionality to call patients for their second dose.



Section 11: COVID-19 Requirements for IISs or Other External Systems

Instructions:

A. *Describe your jurisdiction's solution for documenting vaccine administration in temporary or high-volume vaccination settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution). Include planned contingencies for network outages or other access issues.*

DelVax has a mobile component that will be used for offsite locations. This solution does not require internet access, instead, the data is loaded to the iPads and will be uploaded to DelVAX once they return to the office. Back-up would be a manual process to be entered once they return to the office. Additional training is under way for DPH personnel for its use.

B. *List the variables your jurisdiction's IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.*

Administrated at location: facility name/ID

Administered at location: type

Administration address (including county) ?

Administration date

CVX (Product)

Dose number

IIS Recipient ID

IIS vaccination event ID ?

Lot Number: Unit of Use and/or Unit of Sale

MVX (Manufacturer)

Recipient address*

Recipient date of birth *

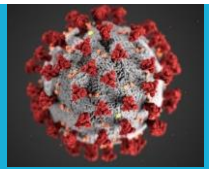
Recipient name*

Recipient sex

Sending organization ?

Vaccine administering provider suffix ?

Vaccine administering site (on the body)



Vaccine expiration date

Vaccine route of administration

Vaccination series complete

Recipient ethnicity

Recipient race

Vaccination Refusal (Y/N)

? These data elements are collected in the IIS. Delaware is consulting with the IIS vendor to assess if these elements can be included in HL7 messages.

* Identifiable Data Elements

C. *Describe your jurisdiction's current capacity for data exchange, storage, and reporting as well as any planned improvements (including timelines) to accommodate the COVID-19 Vaccination Program.*

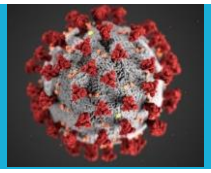
DelVAX System Infrastructure is hosted outside of the State using cloud-based technology and has storage and back up support. Through our vendor as a participant in the CDC program IZ Gateway we have the capacity to exchange data with neighboring States and jurisdictions. Delaware is prepared to produce the reporting requirement to the CDC.

The enhancements below are scheduled to be completed by January 1, 2021, but, although helpful, these enhancements are not integral to the plans for data exchange, storage and reporting of COVID-19 vaccine:

- A streamlined provider registration process to fast track pandemic providers so they can leverage DelVAX to gather patient and COVID-19 vaccinations
- A consumer facing portal that allows Delaware to access and print their own and their children's COVID-19 immunization records
- An expanded DelVAX Vaccination Reminder/Recall capability to target contact of COVID-19 priority group patients
- Implement the use of address verification software (SmartyStreets) for data at rest that will enhance reminder recall capacity in DelVAX.

D. *Describe plans to rapidly enroll and onboard to the IIS those vaccination provider facilities and settings expected to serve healthcare personnel (e.g., paid and unpaid personnel working in healthcare settings, including vaccinators, pharmacy staff, and ancillary staff) and other essential workers.*

Delaware will be using the Provider Management module within DelVAX to enroll practices for Covid-19 immunization program. Delaware's IIS vendor is working to create an exportable provider enrollment file that will be uploaded into CDC's Immunization Data Lake twice weekly



and should be ready for use by November 7, 2020. Delaware is prepared to have providers complete paper enrollment forms and to manually create the twice weekly provider enrollment file to send to CDC if the vendor is unable to meet the deadline.

E. *Describe your jurisdiction's current status and plans to onboard to the IZ Gateway **Connect** and **Share** components.*

Delaware is already a participant in IZ Gateway Share and are in the process of getting the Data Use Agreement (DUA) signed for Connect.

F. *Describe the status of establishing:*

1. Data use agreement with the Association of Public Health Laboratories to participate in the IZ Gateway

   Work is in progress to sign agreement.

2. Data use agreement with CDC for national coverage analyses

   Waiting for the CDC to finalize the document.

3. Memorandum of Understanding to share data with other jurisdictions via the IZ Gateway Share component

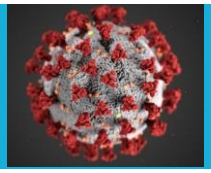
   MOU is signed by Delaware and is exchanging data with the City of Philadelphia and the State of Maryland. Other bordering states (New Jersey, Pennsylvania, Virginia and Washington D.C.) will be asked to participate in the future.

G. *Describe planned backup solutions for offline use if internet connectivity is lost or not possible.*

DelVAX has a Mobile component that will be used for offsite locations. This solution does not require internet access, instead, the data is loaded to the iPads and will be uploaded to DelVAX once they return to the office. Plans are to "test" the mobile component at community influenza clinics in October 2020.

H. *Describe how your jurisdiction will monitor data quality and the steps to be taken to ensure data are available, complete, timely, valid, accurate, consistent, and unique.*

Utilizing tools in DelVAX we can monitor data quality using the Traffic Analysis tool to review incoming messages, message log tool which shows warnings and errors in the messages, and reports.



Section 12: COVID-19 Vaccination Program Communication

Instructions:

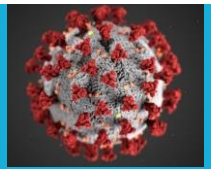
A. *Describe your jurisdiction's COVID-19 vaccination communication plan, including key audiences, communication channels, and partner activation for each of the three phases of the COVID-19 Vaccination Program.*

Key audiences, many of whom have established partnerships prior to and during COVID-19:

- First Responders (Health care workers, police, EMS, fire)
- Older individuals (i.e. Long-term care facilities, senior centers, 55+ communities and towns/municipalities with older populations)
- Other vulnerable populations (immunocompromised, chronic or underlying medical conditions – cancer, diabetes, stroke, lung/heart/kidney disease)
- Diverse populations (African American communities, Hispanic/Latino, etc.)
- Uninsured/underinsured Delawareans
- Legislators
- Employers (including state, county and municipal government)
- Community partners and stakeholders

Communication channels:
DPH is working closely with AB&C, marketing and communications firm, to develop and subsequently implement clear and concise messaging regarding the COVID vaccine. Messages will be tailored to key audiences to ensure they are understood and accepted by members of various populations and communities. Messaging during COVID-19 has been translated into Spanish and Haitian-Creole given the population composition in Delaware. The planned communication channels will include:

- Social media (Facebook, Twitter, Instagram)
- Press briefings
- Press releases
- Radio
- Publications utilized by Delaware's Hispanic community
- Billboards
- Other digital media: Pandora, Spotify, ad theorent display network, Taboola Native Display



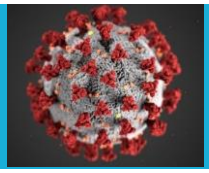
- E-blasts
- DE Health Alert Network
- Community influencers

Partner activation:
DPH will ask for assistance with outreach from:

- Schools, school nurses, parents, children
- College/university health centers
- FQHCs
- State/county chambers
- Faith-based partners
- Non-profit associations
- Legislators
- Employers – private, state, county and municipal
- Delaware Healthcare Association and its member Hospital systems
- Local pharmacies: CVS, Rite-Aid, and Walgreens
- Medical Society of DE and medical practices
- Black, Latino and Haitian Creole community organizations
- Immunization Coalition

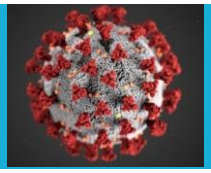
B. *Describe your jurisdiction's expedited procedures for risk/crisis/emergency communication, including timely message development as well as delivery methods as new information becomes available.*

In the event of emergency communications, the DPH Office of Communications (OComms) will closely follow the Continuity of Operations Plan as well as the Crisis and Risk Communications Annex plan. OComms will work in tandem with the DHSS Communications Office, the Delaware Management Agency, the Governor's Office, and any other agency to ensure fast and accurate information is presented to the public. This will include but is not limited to updating scripts for the COVID-19 Call Center, drafting and sending press releases, drafting and posting social media, and handling inquiries from the media when subsequent questions are asked of DPH.



To deliver an evolving message, OComms will rely heavily on social media as well as the local press to distribute its information in press release form to as wide an audience as possible, as well as utilize relationships with faith-based and community partners which have been enhanced during the COVID-19 response. The Crisis and Risk Communications Annex contains draft press releases for various scenarios, including vaccine distribution and distribution events.

OComms will also work closely with public information officers at local schools, hospitals, long-term care facilities, FQHCs, and shelters to ensure the information is disbursed to as wide an audience as possible. OComms will also continue to communicate information with community groups such as faith-based organizations, tribal organizations, and African American and Latino populations.



Section 13: Regulatory Considerations for COVID-19 Vaccination

Instructions:

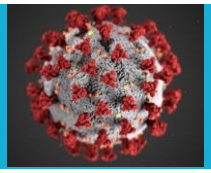
A. *Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.*

Evaluate past procedures during the H1N1 vaccination response. Use current processes/procedures to enroll providers in the Immunization Information System (IIS) to ensure reporting of vaccinations, such as with Vaccines For Children (VFC) and influenza vaccinations. Expand on current enrollment processes for COVID-19 testing. Creating a COVID webpage that will be added to the existing Immunization Program web site to include all the necessary documents related to enrollment, vaccine administration, to include links to the EUA and VIS for easy access for distribution to their patients.

B. *Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.*

Use current processes/procedures for immunizations regarding VISs and documentation such as VFC and influenza vaccinations. Evaluate past practices during H1N1. Expand on current registration, which includes using the IIS for registration and documentation processes for COVID-19 testing. Use current process for Remdesivir regarding EUA fact sheet distribution. Provide a web site for all necessary documents related to enrollment, vaccine administration, to include links to the EUA and VIS for easy access for distribution to their patients.

- https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

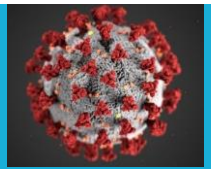


Section 14: COVID-19 Vaccine Safety Monitoring

Instructions:

A. *Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).*

Provide information on COVID web page on the options on how to report Vaccine Adverse Events, which is standard practice for Delaware Providers. The link to VAERS (https://vaers.hhs.gov) will be posted with instructions on how to report. Vaccine Planning Group will evaluate past practices that occurred during the H1N1 vaccine response. The planning group will also evaluate current procedures on reporting adverse events for Remdesivir.



Section 15: COVID-19 Vaccination Program Monitoring

Instructions:

A. *Describe your jurisdiction's methods and procedures for monitoring progress in COVID-19 Vaccination Program implementation, including:*

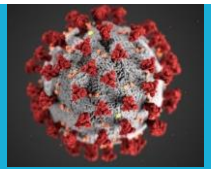
- Provider enrollment
  - Compare provide enrollment data in the IIS versus recruitment outreach efforts.
- Access to COVID-19 vaccination services by population in all phases of implementation
  - Surveillance through Immunizations and Epidemiology with public reporting through My Healthy Community data portal
- IIS or other designated system performance
  - Monitor IIS system performance via reports from vendor to determine performance shortfalls
- Data reporting to CDC
  - Monitor Immunization reporting to IZ Gateway using established IIS reports
- Provider-level data reporting
  - Using established IIS reports, provide data on reporting for inclusion to My Health Community data portal
- Vaccine ordering and distribution
  - Using established VTrckS data downloaded to incorporate into the My Healthy Community data portal or use the "Tiberius" program to incorporate data.
- 1- and 2-dose COVID-19 vaccination coverage
  - Using established IIS Coverage Rate Reports to monitor progress. Further enhancements may be needed to review demographic coverage rates.
  - Routine meeting with stakeholders to cover data reporting, IIS performance, provider surveys and epidemiological surveillance.

B. *Describe your jurisdiction's methods and procedures for monitoring resources, including:*

- Budget
  - Immunization Program manages grant budget using OMD established fiscal process. Preparedness monitors ELC budget fiscal process.
- Staffing
  - SHOC in coordination with vaccine planning group will manage staffing for preparedness events and SHOC staffing.
- Supplies
  - Similar process will be used by the Preparedness Section that is currently underway with COVID-19 testing resources.

C. *Describe your jurisdiction's methods and procedures for monitoring communication, including:*

- Message delivery



- Office of Health Risk Communications (OHRC) serves as the Public Information Hub for any response activity when the SHOC is activated.

- Reception of communication messages and materials among target audiences throughout jurisdiction
  - The Office of Communications (OComms) disseminates the information for public consumption for any response activity when the SHOC is activated. OComms has website analytics to monitor and evaluate access to information and determine effectiveness of messaging through websites and social media.

D. *Describe your jurisdiction's methods and procedures for monitoring local-level situational awareness (i.e., strategies, activities, progress, etc.).*
   - A similar process will be used that is underway with COVID testing. A review of the data from the IIS, Epidemiological Surveillance. With data viewed on the My Healthy Community data portal, with DPH reviewing to determine progress.

E. *Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, vaccination coverage), if any, that will be posted on your jurisdiction's public-facing website, including the exact web location of placement.*
   - Track on the My Health Community data portal, mimicking testing data, similar to flu.delaware.gov and COVID-19 websites, with plans to include based on available data and technological capabilities:
     i. Vaccination sites
     ii. Vaccination provider enrollment
     iii. Doses distributed
     iv. Doses administered
     v. Vaccination coverage capturing race/ethnicity
     vi. Percent infection in vaccinated population

Appendix A-Vaccine Transport

SECTION SIX: Vaccine Transport

Transport, as described in this section, involves the movement of vaccine between providers or other locations over a shorter distance and time frame and is appropriate for events such as an emergency, off-site clinic, or to ensure vaccines that are about to expire can be used rather than wasted.

Vaccine Transport Situations

Vaccine transport to off-site or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and time frame for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised (e.g., because of power loss). Depending on the situation, some transport recommendations may be the same, but there are also some differences.

Vaccine Transport

Vaccines from your supply should not be routinely transported. In instances where the transport of vaccine from your supply is necessary, take appropriate precautions to protect your supply. Vaccines should only be transported using appropriate packing materials that provide the maximum protection.

Protecting your vaccine supply

- Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility.
- If delivery to the specific site is not possible, then vaccine can be transported in a stable storage unit and monitored with a TMD. If the facility doesn't have the capacity to refrigerate the vaccines, then a portable vaccine storage unit or qualified container and packout may be used with a DDL.
- Develop an emergency plan or SOPs for transporting vaccines and include procedures and protocols for packing and transport.

Partially used vials cannot be transferred between providers OR across state lines.*

- **The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).**
- **Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.**
- **Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory. Appropriate materials include:**
  - Portable vaccine refrigerator/freezer units (preferred option)
  - Qualified containers and packouts
  - Hard-sided insulated containers or Styrofoam™ (Use in conjunction with the *Packing Vaccines for Transport during Emergencies*† tool. This system is only to be used in an emergency.)
  - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4° C to 5° C
  - Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
  - TMDs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

The same shipping materials the vaccines were initially shipped in should rarely, if ever, be used as they are not meant for reuse. This could put the cold chain and, ultimately, the viability of the vaccine, at risk.

* Contact your immunization program for details about specific state or local regulations impacting this activity.

† Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

Appendix B-Vaccine Transfer Log

DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
Immunization Program

IMMUNIZATION PROGRAM

Vaccine Transport/ Transfer Log

INSTRUCTIONS: Contact the Immunization Program obtain approval to transfer publicly funded vaccines. Once approved please complete the form and fax to the Immunization Program (302-739-2555) after transfer is complete. A program representative will contact if there are questions regarding the disposition of the vaccine. If you have any questions or concerns, please call (800) 282-8672. Use additional sheets if necessary.

Provider Name:		PIN:		Contact:	
Street Address:		City:		Phone:	
Transferred To:		PIN:		Contact:	
Street Address:		City:		Phone:	
Person Transferring Vaccine:				Phone:	
Immunization Staff Approval obtained on (date & time):			Name of Imm Staff approving transfer:		

VACCINE TRANSFER DUE TO: ☐ Power Outage ☐ Excess Supply ☐ Short Dated ☐ Unit Malfunction ☐ Other _____

Vaccine Inventory Information

Vaccine	NDC	Lot #	Exp	# Doses	Fund Type	Previously Transport? Yes/No	Previously exposed to out of range temps? Yes/No	Comments (add dates and outcome info of previously transported or exposed vaccine incidents that pertain to inventory listed)

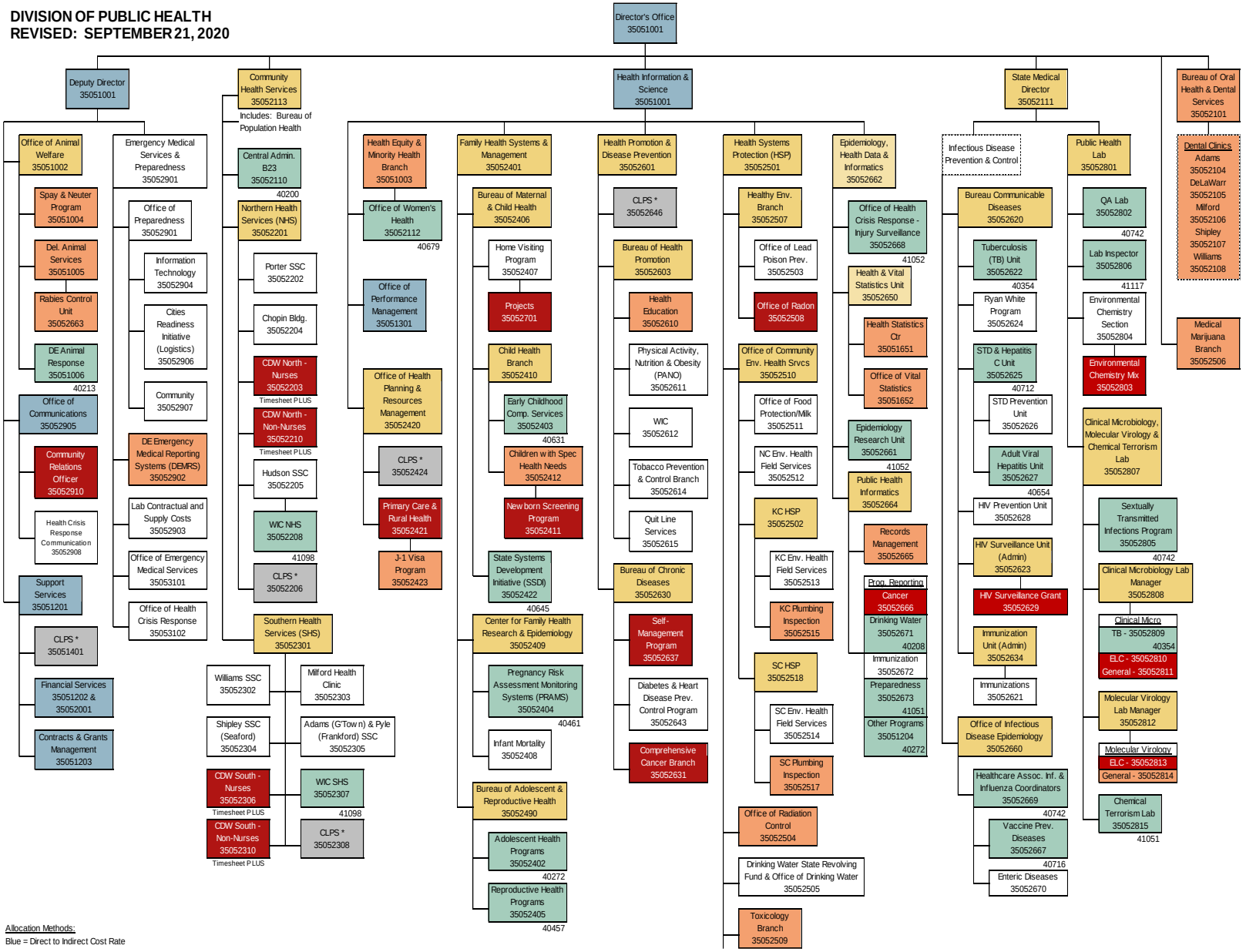
Transport Equip Temp @ Pick Up:		Transport Equip Temp @ Drop Off:
Date & Time of Pick Up:	Date & Time of Drop Off:	Total Transport Time:

Provider Staff Signature: _____ Signature of Receiving Provider Staff: _____

Printed Name: _____ Printed Name: _____

FAX FORM TO (302) 739-2555

Appendix C: DPH Org Chart



Appendix D: SHOC Org Chart